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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,617 | 01/16/2001 | Gene A. Bornzin | A01P1002 | 7875 |

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EXAMINER

OROEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 04/08/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/764,617

Applicant(s)

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/03 (Request for Reconsideration).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. Claims 1-8, 10-12 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Sholder (US 4817605). Sholder discloses a system to automatically periodically optimize the pacing stimulation width and amplitude, the process including review of capture verification (col. 11 @ 11-25). The implantable device is programmed to automatically run the program (col. 11 @ 20-25; col. 6 @ 2-20). The medical practitioner can operate the review process remotely (col. 3 @ 2-7). The presence of a captured cardiac event and the absence of capture cardiac events when the capture cardiac events are expected is automatically determined and visually represented (col. 10 @ 18-67; col. 10 @ 6-18). The control means recognizes capture or non-capture and generates a visual representation of the events on the monitor for practitioner examination and analysis (col. 10 @ 50-67; col. 7 @ 50 – col. 8 @ 7; col. 3 @ 25-46).

As to claims 2 and 3, atrial or ventricular capture verification, read as a plurality of unique means for verifying capture, is selected for analysis by the selection means (col. 5 @ 3-8; col. 6 @ 2-20) .

As to claims 4, 6, 8 and 19, atrial and ventricular cardiac events are detected, identified in the visual representation based on pulse width and amplitude characteristics, and the data recorded (col. 9 @ 1-24; col. 6 @ 22-26; col. 10 @ 15-18).

As to claims 10 and 12, an adjustment by the comparator (146) and controller (148), read as providing a safety margin, is added to the threshold to ensure capture. All the associated capture information in memory can be displayed (col. 9 @ 56-62; col. 10 @ 38-67).

As to claim 11, the programmer can select the use of the autothreshold means (col. 11 @ 20-25; col. 6 @ 6-26).

As to claim 17, an intracardiac electrogram is used to verify capture (col. 6 @ 33-36).

As to claim 18, a surface electrocardiogram is used to verify capture (col. 6 @ 36-38).

2. Claims 1-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Mann et al. (US 5891178). Mann et al. disclose a programmer for use with an implanted medical device.

As to claims 1, 15, 16 and 22, the capture verification process is automated to detect capture and lack of capture (col. 2 @ 50-55; col. 24 @ 1-59). The system is configured to operate remotely (col. 12 @ 45-52). The stability and lengthening of time intervals is indicative of capture and loss of capture respectively (col. 16 @ 18-24; col. 17 @ 7-10). The CPU (504) is read as the control means (col. 12 @ 53-60). A display means provides a visual representation of the events (col. 7 @ 20-23).

As to claims 2 and 3, a plurality of unique means for automatic capture verification, read as atrial and ventricular capture verification tests, are disclosed and are selectable by the user (col. 15 @ 4-7; col. 16 @ 58-65).

As to claims 4-7, 9, 15, 20, and 22, atrial and ventricular events are detected and identified using markers (col. 4 @ 30-34; col. 5 @ 3-9; col. 7 @ 31-35; col. 15 @ 43-59).

As to claims 8 and 19, the amplitude and width, read as duration, are monitored (col. 6 @ 47-58; col. 15 @ 43-59)

As to claims 10-11 and 21, a safety margin, is added to the pacing threshold value to ensure capture, and the autothreshold test is selectively activated by the programmer (figure 8; col. 14 @ 44-47; col. 16 @ 30-43; col. 17 @ 7-12; col. 2 @ 60 – col. 3 @ 10).

As to claims 12-14, the additional visual representation can be an internal or external printer (col. 6 @ 5-8).

As to claim 17, an intracardiac electrogram is used to verify capture (col. 4 @ 22-34 and 53-57; col. 6 @ 9-26; figures 18 and 19).

As to claim 18, a surface electrocardiogram is used to verify capture (col. 4 @ 22-34 and 53-57; col. 6 @ 9-26; figures 18-19).

Statutory Basis

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

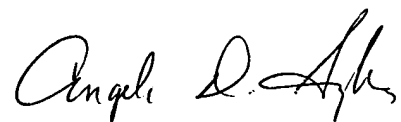
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
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Art Unit 3762

4/2/03



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